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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,563	10/31/2003	Najla Guthrie	182718-335142	8415

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DAVIDSON, DAVIDSON & KAPPEL, LLC  
485 SEVENTH AVENUE, 14TH FLOOR  
NEW YORK, NY 10018

EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/697,563	<b>Applicant(s)</b> GUTHRIE ET AL.	
	<b>Examiner</b> Kevin E. Weddington	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2-7-05</u> . | 6) <input type="checkbox"/> Other: _____  |

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Claims 15-24 are presented for examination.

Applicants' information disclosure statement filed February 7, 2005 and the amendment filed May 23, 2005 have been received and entered.

Accordingly, the rejection made under 35 USC 112, second paragraph a set forth in the previous Office action dated February 24, 2005 at page 2 is hereby withdrawn.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15 and 20-23 are again rejected under 35 U.S.C. 102(b) as being anticipated by Bok et al. (6,096,364) of PTO-1449, of record, for reason of record as set forth in the Office action dated February 24, 2005 as applied to claims 8, 13-15 and 20-23.

Applicants' remarks regarding the prior art, Bok et al., does not teach a method of reducing serum insulin levels in a mammal comprising administering an effective amount of at least one polymethoxyflavone compound to reduce the serum insulin levels by at least about 26% are not persuasive since Bok et al. teach polymethoxyflavones are well-known to low blood glucose levels (one symptom associated with metabolic syndrome, see THE MERCK MANUAL of MEDICAL INFORMATION at page 922) would inherently reduce or lower serum insulin levels,

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another symptom or complication associated with insulin resistance as disclosed in the same information set forth in THE MERCK MANUAL of MEDICAL INFORMATION.

The rejection made under 35 USC 102 is adhered to.

Claims 15 and 20-23 are not allowed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-17, 20 and 21 are again rejected under 35 U.S.C. 102(b) as being anticipated by Kurowska et al., "Hypolipidemic activities of tangeretin, a flavonoid from tangerine in vitro and in vivo", Annual Meeting of the Federation of American Societies for Experimental Biology on Experimental Biology March 7, 2001 of PTO-1440 of record, for reason of record as set forth in the Office action dated February 24, 2005 at pages 3 and 4 as applied to claims 8-10, 13-17, 20 and 21.

Applicants' remarks regarding the prior art, Kurowska et al., does not teach a method of reducing serum insulin levels in a mammal comprising administering an effective amount of at least one polymethoxyflavone compound to reduce the serum insulin levels by at least about 26% are not persuasive since Kurowska et al. teach tangeretin, a polymethoxyflavone, is used to treat high cholesterol levels, a complication associated with insulin resistance as disclosed in THE MERCK MANUAL OF MEDICAL INFORMATION, page 922. Again, as stated on page 922 of THE MERCK

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MANUAL, "many people with metabolic syndrome (insulin resistance syndrome) need to take lipid-lowering agents. Clearly, the administration of tangeretin would inherently reduce serum levels of insulin in the absence of evidence to the contrary.

The rejection made under 35 USC 102 is adhered to.

Claims 15-17, 20 and 21 are not allowed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 19 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bok et al. in view of Kurowska et al., all of record, for reasons of record as set forth in the Office action dated February 24, 2005 at pages 4-6 as applied to claims 11, 12, 18 and 19.

Applicants' remarks regarding the two prior art references, Bok et al. or Kurowska et al., do not teach the a method of reducing serum insulin levels in a mammal comprising administering an effective amount of least one polymethoxyflavone compound or teach the a mixture of polymethoxyflavones are not persuasive since the instant rejection is based upon the well established principle of patent law that no invention resides in combining 2 or more ingredients of known character, where the results obtained are no more than the additive effects of the

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individual ingredients. It has not been demonstrated on the record by means of experimental data commensurate in scope with the claimed subject matter that applicants' combination produces any unobvious or unexpected results. The mere arguments of applicant are insufficient to overcome the strong prima facie case of obviousness without the experimental data.

The rejection made under 35 USC 103 is adhered to.

Claims 18, 19 and 24 are not allowed.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

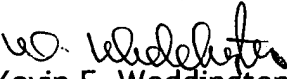
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington  
August 4, 2005